

**REMARKS:**

Reconsideration of the rejections set forth in the Final Office Action mailed December 11, 2007 and entry of the present amendment is requested because Applicants respectfully submit that the Amendment places the application in condition for allowance or in better form for consideration on appeal.

In response to the Final Office Action, claim 82 has been amended to include the limitations of claim 84, and claim 84 has been canceled without prejudice. Accordingly, claims 52-55, 66-68, 70-78, 80-83, and 85-107 are currently pending.

In addition, in Applicants' previous response, claim 55 was erroneously reproduced as depending from claim 50. However, claim 55 was amended to depend from claim 52 in Applicants' response filed April 28, 2005. Accordingly, claim 55 has been amended herein to depend properly from claim 52. No new matter has been introduced.

In the Final Office Action, claim 55 was objected to, and claims 82, 83, 85-94, 97, and 99-107 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,250,307 ("the Conrad et al. reference"). In addition, claims 52-54, 66-68, 70-78, 81, and 98 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Conrad et al. reference. Because the cited reference does not disclose, teach, or suggest the subject matter of the present claims, the rejections should be withdrawn.

As an initial matter, Applicants appreciate the Examiner's indication that claims 84 and 95 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 82 has been amended to include the limitations of dependent claim 84, which has therefore been canceled without prejudice. Accordingly, claims 82

and its dependent claims, 83 and 85-92 should now be allowable. Claim 95 will be addressed when the final status of the application is determined.

With respect to the objection to claim 55, claim 55 has been amended to depend properly from claim 52, as explained above.

Turning to the Conrad et al. reference, implants are disclosed for implantation within the soft palate for treating snoring. Col. 2, lines 21-26. In one embodiment, shown in FIGS. 11-16, the implant 20 is a flexible strip that has a length of about 20-30 mm and a width of 5-10 mm. Col. 5, lines 30-41. In another embodiment, shown in FIGS. 20-23, the implant 30 has an oval shape to cause deformation of the geometry of the soft palate. Col. 7, lines 5-8. Although the implant 30 may be expanded mechanically, the Conrad et al. reference discloses that the implant 30 is preferably formed as a shape-memory alloy that expands to the enlarged (oval) shape in response to the warmth of the body. Col. 7, lines 11-16. The Conrad et al. reference does not provide any further description of the implant 30 and no drawings other than the cross-sectional views of FIGS. 20-23.

Presumably, however, the implant 30 would have a width similar to the strip 20 described in col. 5, i.e., a width of 5-10 mm. Otherwise, when the implant 30 begins to expand within the soft palate, there would be substantial risk of the implant 30 tearing through or otherwise damaging the tissue of the soft palate, rather than merely changing the shape of the soft palate. In particular, the Conrad et al. reference does not teach or suggest that the implant 30 may be formed from a wire, because such a relatively narrow implant 30 would apply an expansion force on a very small area of adjacent tissue, as compared to a wider implant, which would apply a more uniform expansion force over a larger area. In addition, given the limitations of the anatomy

of the soft palate, as shown in FIGS. 11, 22, and 23, the length of the implant 30 would likely be no longer than the implant 20, i.e., about 20-30 mm. Otherwise, the implant 30 would not fit within the soft palate, as shown in FIGS. 11, 22, and 23 of the Conrad et al. reference.

Turning to the present claims, claim 52 recites a method for treating sleep apnea in a human or an animal having an oropharyngeal region with lateral and posterior walls, a soft palate, a vallecular space and an epiglottis that includes providing an appliance made of a biocompatible metal below a soft palate of a human or animal in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of the human or animal, the appliance so provided having at least two laterally positioned elements substantially longitudinally spaced apart from each other to define an open interior space therebetween and providing an opening force against the lateral walls of the oropharyngeal region.

First, as explained above and in Applicants' response filed June 23, 2006, the Conrad et al. reference fails to disclose, teach, or suggest anything about providing an appliance *below a soft palate* in or radially outwardly from *the lateral and posterior walls of an oropharyngeal region*, as claimed. Instead, the Conrad et al. reference discloses implants that implanted within the soft palate. As explained in Applicants' June 23, 2006 response, pages 12-13, these are anatomically and functionally different regions of the body.

Further, given the substantial anatomical differences between these two regions, it would not be obvious to provide the Conrad et al. implant within an oropharyngeal region. As explained above, the Conrad et al. implant 30 would likely be no longer than 20-30 mm. Given the size of the oropharyngeal region, such an implant would be too small to be securely received within the oropharyngeal region. For example, as described at page 8, lines 28-31 and as recited in claim 98

of the present application, the appliance may expand to a diameter greater than 32 mm in the deployed configuration, e.g., to engage the posterior and lateral walls of the oropharyngeal region. An implant whose entire length was less than 20-30 mm would be incapable of expanding to such a diameter. Thus, a person of ordinary skill would appreciate that the Conrad et al. implant would be too small for use in the oropharyngeal region.

Further, given the likely 5-10 mm width of the Conrad et al. implant, even if the implant 30 were somehow long enough to be provided within the oropharyngeal region, once so placed, the implant would extend 5-10 mm into the interior of the oropharyngeal region, which would substantially obstruct the passageway therethrough. For these reasons, claim 52 and its dependent claims are not obvious over the Conrad et al. reference.

Turning to claim 93, an apparatus for treating at least one of sleep apnea and snoring is recited that includes an appliance comprising an elongated loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions, the appliance being sized for introduction into an oropharyngeal region of a human or animal and deployable in a C-shaped deployed configuration in which at least one of the elongated elements extends generally laterally across the posterior wall and the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region.

The Conrad et al. reference fails to teach or suggest an appliance *sized for* introduction into an oropharyngeal region in which at least one of the elongated elements *extends generally laterally across the posterior wall* and the first and second end portions *bear against and provide an opening force against the lateral walls* of the oropharyngeal region, as claimed. Instead, as explained above, the Conrad et al. reference discloses an implant whose size is too small to extend

across the posterior wall and bear against the lateral walls of the oropharyngeal region. This difference is emphasized in claim 98, which expressly recites that the appliance expands to *a diameter greater than 32 mm* in the deployed configuration. Accordingly, for these reasons, claim 92 and its dependent claims are neither anticipated by nor otherwise obvious over the Conrad et al. reference.

For similar reasons, claim 100 and its dependent claim are also neither anticipated by nor otherwise obvious over the Conrad et al. reference.

Finally, claim 102 recites a method for treating at least one of sleep apnea and snoring that includes providing an appliance comprising a continuous loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions; introducing the appliance into an oropharyngeal region; and releasing the appliance within the oropharyngeal region such that the elongated elements extends generally laterally across the posterior wall and the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region.

First, as explained above, the Conrad et al. reference fails to disclose, teach, or suggest anything about releasing an appliance within an oropharyngeal region. Thus, for this reason alone, claim 102 and its dependent claims are not anticipated by the Conrad et al. reference.

Second, the Conrad et al. reference does not teach or suggest releasing an appliance within the oropharyngeal region such that the elongated elements extends generally laterally across the posterior wall and the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region. As explained above, the Conrad et al. implant would be too small to extend across the posterior wall and bear against the

lateral walls of the oropharyngeal region. Further, even if somehow long enough, given the width of the Conrad et al. implant, a person of ordinary skill would appreciate that the implant would obstruct the passageway through the oropharyngeal region. Accordingly, for these reasons, claim 102 and its dependent claims are also not obvious over the Conrad et al. reference.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,  
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